K102512

RMS® MEDICAL PRODUCTS

# 510(k) Summary

MAY 2 0 2011

**[As required by 21 CFR 807.92]**

1. **Submitter:** Repro-Med Systems, Inc. dba RMS Medical Products
24 Carpenter Road
Chester, NY 10918 USA
845-469-2042 Fax 845-469-5518

**Contact Person(s):** Andrew Sealfon, President & CEO

**Prepared on:** April 25, 2011

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2. **510k Number:** K102512

**Trade Name:** RMS Subcutaneous Needle Set

**Classification Name:** Intravascular Administration Set

**Classification Code:** FPA (per 21 CFR 880.5440)
Class II

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3. **Predicate Devices:** Evans Medical, Inc.
Evans Sub-q MC4206
K020530

Marcal Medical, Inc.
Subcutaneous Needle Infusion Set
K082818

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4. **Device Description:**
The RMS Subcutaneous Needle Set is a Class II Intravascular Administration Set per 21 CFR 880.5440 and intended for the delivery of medication to the subcutaneous tissue. Each set consists of a sterile packaged kit including the infusion set and a commercially available adhesive dressing used to hold the device in place. The infusion set has a 90-degree stainless steel needle mounted to a butterfly on one end, and a luer lock on the other end, connected by medical grade tubing. Each set is equipped with a slide clamp used to stop flow immediately, as well as a snap together capture arrangement used to close the set upon completion. RMS Subcutaneous Needle Sets are available as single sets, as well as 2-needle, 3-needle, 4-needle, 5-needle and 6-needle assemblies, with the use of a low residual volume Y or multi-connector. The device is for single use only.

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**5. Indications for Use**

RMS Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue for use not to exceed 24 hours.

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**6. Characteristics**

RMS Subcutaneous Needle Sets are identical in performance, physical properties, using similar materials, and having the same indications for use as the predicate devices. Although the design differs in tubing length and needle gauge, performance testing shows that the performance and residual volume of the 26 gauge needle and 20" tubing has equal to or better flow characteristics as compared to the 27 and 24 gauge 36 inch sets, therefore no new issues of safety or effectiveness are introduced by these changes.

| Predicate Device Comparison Chart | | | |
|---|---|---|---|
| **Characteristic** | **RMS Sub-q Set K102512 (New)** | **Evans Sub-q Set K020530** | **Marcal Sub-q Set K082818** |
| Tubing Length (inches) | 20 | 2, 4, 3.5, 5, 36, 42 | 36, 42 |
| Tubing Material | Medical Grade PVC Plastic | Medical Grade Polyethylene Plastic | Medical Grade PVC Plastic |
| Needle Material | Stainless Steel | Stainless Steel | Stainless Steel |
| Needle Gauge | 26 | 24, 27 | 24, 27 |
| Needle Length (mm) | 6, 9, 12 | 4, 6, 9, 12, 14 | 6, 9, 12, 14 |
| Sterilization Method | Gamma | ETO | ETO |
| Indications for Use | RMS Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue. | Evans Winged Subcutaneous Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. | The Subcutaneous Infusion Set is designed specifically for the delivery of medication to the subcutaneous tissue. |



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**Materials Comparison:**

| Materials Comparison Chart | | | | |
|---|---|---|---|---|
| | **Female Luer** | **Tubing** | **Butterfly** | **Adhesive Dressing** |
| RMS Needle Sets | PVC | PVC | Polypropylene | Dressing by 3M |
| Evans Sub-q Sets | PVC | Polyethylene | PVC | Dressing by 3M |
| Marcal Sub-q Sets | n/a | PVC | Polyethylene | n/a |

7. **Performance Testing:** Fluid flow rate testing was performed according to RMS "Needle Set Fluid Flow Rate Test Procedure" (SOP 5071) to determine the flow rates of the RMS needle set, compared to the Evans and Marcal needle sets. Results:

**Patency of Lumens (Summary) by Leg and Total Flow Rate**

| Average Normalized Flow Rate Comparison | | | | | |
|---|---|---|---|---|---|
| | Needle | | | | |
| | 1 | 2 | 3 | 4 | Total |
| RMS Medical Products 26G | 491.36 | 479.25 | 502.06 | 513.70 | 1996.35 |
| Evans Medical 27G | 246.40 | 225.49 | 129.73 | 243.31 | 838.98 |
| Evans Medical 24G | 503.25 | 501.82 | 491.84 | 484.00 | 1988.98 |
| Marcal Medical 24G | 1018.61 | 1014.81 | 1037.62 | 1001.03 | 4041.17 |

Priming/Residual volumes also were measured and compared with the predicate devices. The performance testing indicates that the RMS Subcutaneous Needle Sets have similar performance to the predicate devices specifically indicating substantially equivalent fluid flows and residual volumes.

**Priming/Residual Volume Measurements by Needles Connected:**

| **Priming/Residual Volume (ml)** | **RMS Sub-q Set 26g K102512 (New)** | **Evans Sub-q Set 27g K020530** | **Marcal Sub-q Set 27g K082818** |
|---|---|---|---|
| 1-Needle | .074 | .23 | .15 |
| 2-Needle | .245 | .40 | .25 |
| 3-Needle | .417 | .60 | .45 |
| 4-Needle | .588 | .80 | .50 |
| 5-Needle | .760 | 1.00 | .65 |
| 6-Needle | .931 | 1.20 | .80 |



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**Needle Tip Measurements**

A comparison of the needle tip dimensions indicates there is no substantial difference between the RMS needles and the predicate devices.

| Company | Top Angle (degrees) | Side Angle (degrees) | Length (inches) |
|---|---|---|---|
| RMS | 52.3 | 16.5 | 0.018 |
| Evans | 52.3 | 16.5 | 0.022 |
| Marcal | 51.9 | 16.3 | 0.016 |

**Wing Flexibility**

Measurements of wing flexibility indicate that the RMS needles require less force to flex than the predicate devices and thus may be considered equal or better in that regard.

| | RMS | Marcal | Evans Medical |
|---|---|---|---|
| | (grams) | | |
| Butterfly 1 | 20 | 50 | 45 |
| | 18 | 43 | 44 |
| Butterfly 2 | 15 | 44 | 38 |
| | 19 | 40 | 42 |
| Butterfly 3 | 25 | 58 | 32 |
| | 25 | 50 | 38 |
| Butterfly 4 | 28 | 45 | 30 |
| | 23 | 50 | 42 |
| **Mean** | 22 | 48 | 39 |

8. **Biocompatibility:** In accordance with ISO 10993, studies were performed including cytotoxicity, irritation, sensitization, thrombogenicity, and hemocompatability. The Complement Activation GLP Report and Partial Thromboplastin Time study compared the RMS needle sets with the predicate directly with similar acceptable results recorded.



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**Summary of Testing Performed:**

| Test Performed | Standard | Test Name | Test Result | Other name |
|---|---|---|---|---|
| Sterility $10^{-6}$ | ISO 11137-2 | Sterility | PASS | Vdmax |
| Biocompatibility | ISO 10993-5 | Cytotoxicity | PASS | MEM Elution Report |
| Biocompatibility | ISO 10993-10 | Irritation | PASS | Intracutaneous injection test |
| Biocompatibility | ISO 10993-10 | Sensitization | PASS | Magnusson-Kligman Method |
| Biocompatibility | ISO 10993-4 | Hemocompatability | PASS | Complement Activation GLP Report |
| Biocompatibility | ISO 10993-4 | Hemocompatability/clotting | PASS | Partial Thromboplastin Time (PTT) |
| Biocompatibility | ISO 10993-4 | Hemocompatability | PASS | Hemolysis Direct Contact |
| Biocompatibility | ISO 10993-4 | Hemocompatability | PASS | Hemolysis Extract Method |

9. **Substantial Equivalence:** The data presented demonstrates that RMS Subcutaneous Needle Sets are substantially equivalent to the predicate devices in terms of function, safety, performance, intended use, technology/principles, mechanical properties, biocompatibility, and flow. Differences between the RMS Subcutaneous Needle Sets and the predicate devices do not raise any new issues of safety or effectiveness.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 20 2011

Mr. Andrew I. Sealfon
President & CEO
Repro-Med Systems, Incorporated
24 Carpenter Road
Chester, New York 10918

Re: K102512
Trade/Device Name: RMS Subcutaneous Needle Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 6, 2011
Received: May 9, 2011

Dear Mr. Sealfon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Section 4
## Indications for Use Statement

510(k) Number (if known): K102512

**Device Name:**
RMS Subcutaneous Needle Set

**Indications for Use:**
RMS Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

5/20/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102512